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**UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA
 WESTERN DIVISION**

CEDARS-SINAI MEDICAL CENTER,
 a California nonprofit public benefit
 corporation,

Plaintiff,

vs.

**QUEST DIAGNOSTICS
 INCORPORATED,** a Delaware
 corporation, and **QUEST DIAGNOSTICS
 NICHOLS INSTITUTE,** a California
 corporation,

Defendants.

Case No. 2:17-cv-5169-GW-FFM

**SECOND AMENDED
 COMPLAINT FOR:**

- (1) TRADE SECRET
 MISAPPROPRIATION,
 18 U.S.C. § 1836 AND
 CAL. CIV. CODE § 3426;**
- (2) BREACH OF CONTRACT;
 AND**
- (3) PATENT INFRINGEMENT,
 35 U.S.C. § 271**

DEMAND FOR JURY TRIAL

1 Plaintiff Cedars-Sinai Medical Center (“Cedars-Sinai”) alleges as follows for
 2 its Second Amended Complaint against Defendants Quest Diagnostics Incorporated
 3 (“Quest”) and Quest Diagnostics Nichols Institute (“Nichols Institute”) (collectively
 4 with Quest, “Defendants”):

5 **L.R. 8-1 JURISDICTIONAL STATEMENT**

6 1. In accordance with L.R. 8-1, this Court’s jurisdiction is invoked
 7 pursuant to 28 U.S.C. §§ 1331 and 1338(a)-(b), as this case involves federal
 8 questions arising under the trade secret and patent laws of the United States and
 9 related breach of contract, including 35 U.S.C. § 271 *et seq.*, 35 U.S.C. § 154(d), 18
 10 U.S.C. § 1836 *et seq.*, and Cal. Civ. Code. § 3426 *et seq.* This Court has
 11 supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) over the asserted state law
 12 claims.

13 **NATURE OF THE CASE**

14 2. This case concerns Quest’s and the Nichols Institute’s wrongful and
 15 unauthorized exploitation of groundbreaking medical discoveries by Dr. Mark
 16 Pimentel and other physicians at Cedars-Sinai relating to the pathophysiology,
 17 diagnosis, and treatment of irritable bowel syndrome (“IBS”). IBS is the most
 18 common functional gastrointestinal disease. It results in chronic changes in bowel
 19 function, including diarrhea, constipation, and alternating patterns. IBS symptoms
 20 are among the top 10 reasons for patient visits to primary care physicians.
 21 Approximately 15% of the human population suffers from IBS, and approximately
 22 75% of individuals with IBS remain undiagnosed.

23 3. Before the Cedars-Sinai team’s discoveries, longstanding medical
 24 dogma held that IBS was a psychological condition that was diagnosed only by
 25 excluding other, organic conditions. Defying conventional wisdom and public
 26 criticism by the medical establishment, the Cedars-Sinai team discovered an organic
 27 pathophysiology of IBS and developed related diagnostic and treatment innovations
 28 for which numerous patents have been awarded in the United States and abroad.

1 4. Quest boasts on its website that it is “the world’s leading provider of
2 diagnostic testing, information and services that patients and doctors need to make
3 better healthcare decisions.” *See* [http://questdiagnostics.com/home/about/products-](http://questdiagnostics.com/home/about/products-services.html)
4 [services.html](http://questdiagnostics.com/home/about/products-services.html). Keenly aware of the clinical benefits and commercial value of
5 Cedars-Sinai’s IBS discoveries, Quest pretended to be interested in an exclusive
6 license to Cedars-Sinai’s IBS diagnostic technology to gain access to highly
7 valuable information and technical assistance from Dr. Pimentel that otherwise
8 would have been unavailable to Quest. To facilitate discussion of a potential
9 license, the parties entered into contractual obligations of confidentiality
10 (“Confidentiality Obligations”) on or around November 24, 2013, subject to which
11 Quest received extremely valuable trade secrets and other protected information
12 from Cedars-Sinai regarding IBS diagnostic techniques and validation of the same,
13 as well as how to serve unmet clinical needs associated with IBS.

14 5. On or about December 23, 2014, Quest then abruptly informed Cedars-
15 Sinai that Quest was not interested in a license agreement. Consequently, Cedars-
16 Sinai ultimately granted a license to a different diagnostic services provider,
17 Commonwealth Laboratories. Quest’s acknowledgement of the value of Cedars-
18 Sinai’s technology and its proprietary nature is shown by Quest’s use of
19 Commonwealth Laboratories’ licensed diagnostics services to process samples from
20 patients collected through Quest’s network of patient service centers. The license
21 agreement between Cedars-Sinai and Commonwealth Laboratories was terminated
22 in 2017.

23 6. Unbeknownst to Cedars-Sinai until recently, Quest secretly prepared
24 and in or about April 2017 began to commercialize its own IBS diagnostic services
25 through unlawful use of Cedars-Sinai’s trade secrets and patented inventions and
26 through breaches of the Confidentiality Obligations. Cedars-Sinai brings this action
27 to right those wrongs.
28

THE PARTIES

7. Cedars-Sinai is a nonprofit public benefit corporation organized under the California Nonprofit Public Benefit Corporation Law and operated exclusively for charitable purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986 with a principal place of business located at 8700 Beverly Boulevard, Los Angeles, California 90048.

8. Quest is a corporation organized under the laws of Delaware and registered to do business in California with a principal place of business located at 3 Giralda Farms, Madison, New Jersey 07940. Quest maintains numerous regular and established places of business in the Central District of California, including, without limitation, laboratories in West Hills, California, and San Juan Capistrano, California.

9. The Nichols Institute is a corporation organized under the laws of California and registered to do business in California with a principal place of business located in the Central District of California at 33608 Ortega Highway, San Juan Capistrano, California 92675. The Nichols Institute also maintains a regular and established place of business in Valencia, California, which is also located in the Central District of California. On information and belief, the Nichols Institute is a wholly owned subsidiary of Quest.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a)-(b), and 1367(a).

11. This Court has personal jurisdiction over Quest because Quest is registered to do business in California, maintains numerous regular and established places of business in the Central District of California, has breached contractual obligations that were entered into in the Central District of California and are governed by California law, has committed acts of patent infringement and trade secret misappropriation in the Central District of California, and/or otherwise has

1 purposefully directed activities toward the Central District of California that the
2 asserted causes of action arise out of or relate to.

3 12. This Court has personal jurisdiction over the Nichols Institute because
4 the Nichols Institute is a corporation organized under the laws of California, is
5 registered to do business in California, maintains a principal place of business in the
6 Central District of California, has committed acts of patent infringement and trade
7 secret misappropriation in the Central District of California, and/or otherwise has
8 purposefully directed activities toward the Central District of California that the
9 asserted causes of action arise out of or relate to.

10 13. Venue in the Central District of California is proper for Cedars-Sinai's
11 non-patent claims under 28 U.S.C. § 1391(c) for the same reasons alleged in the
12 preceding paragraphs as to why Quest and the Nichols Institute are subject to
13 personal jurisdiction.

14 14. Venue in the Central District of California is proper for Cedars-Sinai's
15 patent claims under 28 U.S.C. § 1400(b). Quest and the Nichols Institute have
16 committed acts of patent infringement in the Central District of California. In
17 addition, Quest has numerous regular and established places of business in the
18 Central District of California, including, without limitation, laboratories in West
19 Hills, California, and San Juan Capistrano, California where infringement has
20 occurred. The Nichols Institute is also a corporation organized under the laws of
21 California, is registered to do business in California, maintains a principal place of
22 business in the Central District of California in San Juan Capistrano, California, and
23 maintains a separate regular and established place of business in the Central District
24 of California in Valencia, California where infringement has occurred.

PATENTS-IN-SUIT

15. Cedars-Sinai is the owner of all right, title, and interest in United States Patent No. 9,702,884 (“’884 Patent”), titled “Methods for Detecting the Presence of Irritable Bowel Syndrome and System for Diagnosing Same,” which was duly and properly issued by the United States Patent and Trademark Office on July 11, 2017 naming Mark Pimentel and Christopher Chang as inventors and Cedars-Sinai as assignee. The publication, Pimentel et al., *Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects*, PLoS One (2015). 10(5): pp. 1-12, is incorporated by reference in the ’884 Patent. A true and correct copy of the ’884 Patent is attached as Exhibit A to this Second Amended Complaint.

BACKGROUND

16. Cedars-Sinai is one of the largest nonprofit academic medical centers in the United States. Cedars-Sinai has consistently been named one of America’s Best Hospitals by U.S. News & World Report, has received the National Research Corporation’s Consumer Choice Award 18 years in a row for providing the highest quality medical care in Los Angeles, and has the longest running Magnet designation for nursing excellence in California.

17. Cedars-Sinai is widely recognized as a leader in clinical care and research. Cedars-Sinai also impacts the future of healthcare through education programs. Cedars-Sinai further demonstrates a longstanding commitment to strengthening the Los Angeles community through wide-ranging programs that improve the health of its most vulnerable residents.

18. In service of its mission to relieve human suffering, Cedars-Sinai has supported decades of research into the pathophysiology of IBS and development of diagnostics and treatments for IBS. Cedars-Sinai licenses the results of that and other research to generate revenues to perpetuate Cedars-Sinai’s continuing research and other charitable endeavors.

1 19. Before Cedars-Sinai's IBS discoveries, the medical community did not
2 have a clear understanding of the pathophysiology of IBS and followed a "diagnosis
3 of exclusion" approach that involved great expense and morbidity for patients with
4 IBS, including frequent body imaging, endoscopy, and blood testing to rule out
5 alternative organic explanations for symptoms. This approach led to extensive
6 waste of expensive health care resources, including drug treatments based on
7 controlling symptoms of IBS rather than its causes, which often caused opposite
8 symptoms.

9 20. Cedars-Sinai's research revealed, among other things, that a majority of
10 IBS cases in the United States population result from a sequence of events
11 precipitated by acute gastroenteritis ("AGE"), colloquially referred to as food
12 poisoning, caused by bacterial infection. The infecting bacteria produce a protein
13 toxin known as cytolethal distending toxin ("Cdt"), which is composed of three
14 subunits, CdtA, CdtB, and CdtC. CdtB is the active component, and CdtA and CdtC
15 are involved in delivering CdtB into cells.

16 21. Using an immunochemical approach, the Cedars-Sinai team discovered
17 that CdtB produces an effect on the host through the production of autoantibodies.
18 Antibodies to CdtB bind to the myenteric neurons and the interstitial cells of Cajal.
19 These autoantibodies are detectable in patients with post-infectious IBS and have a
20 significant diagnostic value in both identifying post-infectious IBS (even in contrast
21 to Crohns and ulcerative colitis) and in predicting the consequence of a small bowel
22 neuropathy, which in turn causes reduced gut motility and consequent small
23 intestinal bacterial overgrowth ("SIBO").

24 22. Cedars-Sinai's team identified a sequence of events leading to this
25 disturbance that starts with exposure to a bacterial pathogen containing CdtB. The
26 resulting immune response to CdtB produces antibodies that also recognize a host
27 enteric nerve cytosolic protein. The resulting autoantibody and its titer correlate
28 with the degree of SIBO, which is an indirect measure of the neuronal impairment

1 of the small bowel.

2 23. Through molecular mimicry, antibodies to CdtB after AGE produce an
3 autoantibody to vinculin. Notably, this anti-vinculin antibody does not exist
4 naturally in a bodily sample. Vinculin is an intracellular protein that does not exist
5 externally to the cell. As a result, circulating anti-vinculin antibodies do not exist
6 naturally in the human body because the human body does not generate immune
7 responses to its own proteins, such as vinculin.

8 24. Detection of the anti-vinculin antibody is predictive of IBS. Titers of
9 anti-CdtB correlate with the degree of SIBO, and neuropathy induced by these
10 antibodies is a cause of SIBO. The degree and presence of SIBO determines the
11 resulting bowel disturbance. And SIBO can be treated with the gut-specific
12 antibiotic rifaximin, which can be safely used on a repeated basis because it tends
13 not to elicit microbial resistance.

14 25. Thus, the Cedars-Sinai team discovered that detection in a biological
15 sample of anti-CdtB and/or anti-vinculin antibodies above certain control levels
16 indicates the presence of IBS, that symptoms of IBS are attributable to SIBO, and
17 that SIBO can be treated with rifaximin. This correlation of anti-vinculin antibodies
18 to the IBS disease state was not previously known.

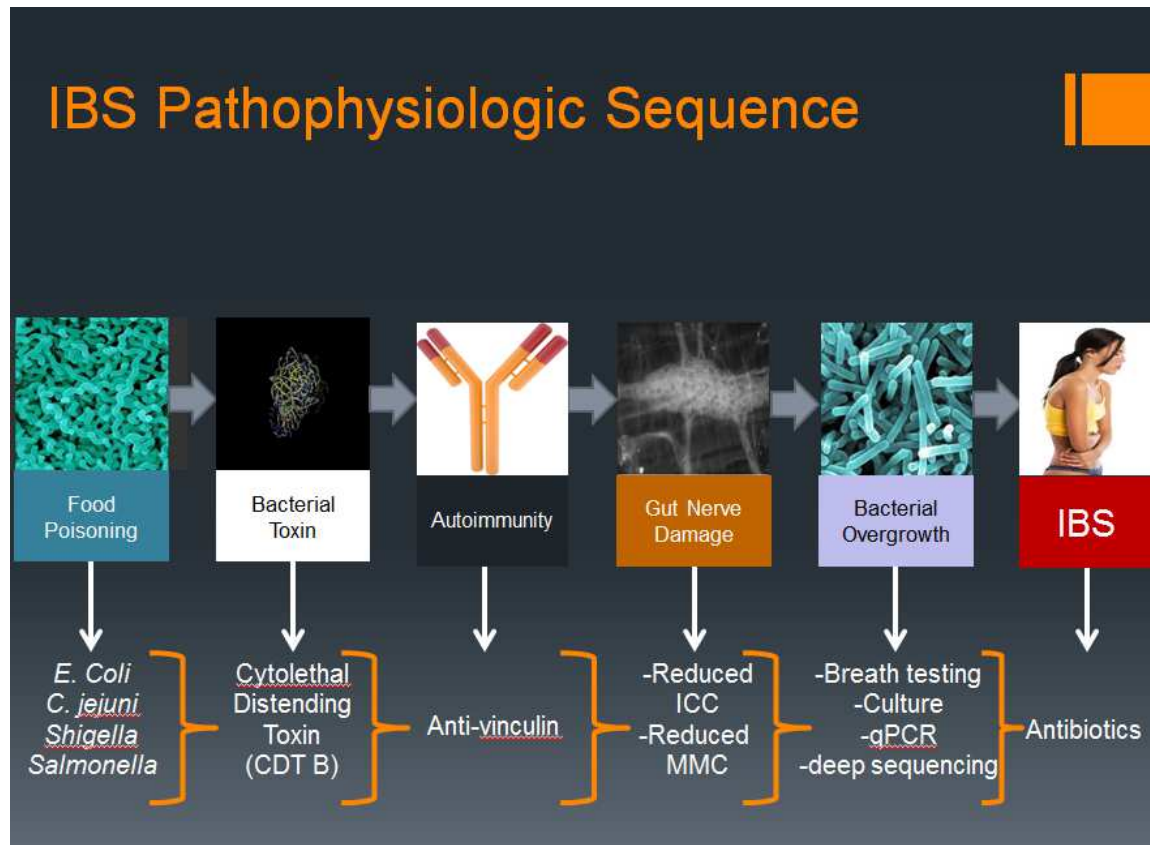
19 26. The Cedars-Sinai team's discovery led to a breakthrough in diagnostic
20 testing for IBS. Quest has acknowledged the breakthrough discovery of the Cedars-
21 Sinai team, including Dr. Mark Pimentel, in part on Quest's website, as follows:
22 "Several years ago, researchers observed a connection between IBS and infection:
23 40% of patients who were diagnosed with IBS-D (diarrhea-predominant IBS) had
24 had a previous bout of acute gastroenteritis or food poisoning. . . . This breakthrough
25 led to the validation of two serum biomarkers, anti-CdtB and anti-vinculin. . . ." See
26 <http://www.questprimaryinsights.com/ibs/>. A true and correct copy of the foregoing
27 website is attached as Exhibit B to this Second Amended Complaint. Quest has also
28 cited the Cedars-Sinai team's breakthrough discovery in its promotional literature,

1 including in an information sheet to physicians, as “[c]onfirm[ing] post-infectious
2 IBS-D and IBS-M with 95% post-test probability” and “[m]ay avoid the
3 unnecessary use of healthcare resources.” A true and correct copy of the foregoing
4 information sheet, available at [http://www.questprimaryinsights.com/wp-](http://www.questprimaryinsights.com/wp-content/uploads/2017/07/IBS-Information-Sheet_Physicians.pdf)
5 [content/uploads/2017/07/IBS-Information-Sheet_Physicians.pdf](http://www.questprimaryinsights.com/wp-content/uploads/2017/07/IBS-Information-Sheet_Physicians.pdf), is attached as
6 Exhibit C to this Second Amended Complaint.

7 27. Indeed, others in the industry have praised the Cedars-Sinai team’s
8 breakthrough in diagnostic testing for IBS. For example, Pri-Med, a provider of
9 continuing medical education, has cited the Cedars-Sinai team’s work and
10 emphasized its importance, including on its website, as follows: “Having an
11 affirmative test for IBS is critical to establish a diagnosis of coexisting IBS
12 especially when other causes of diarrhea such as inflammatory bowel disease (IBD)
13 or celiac disease co-exist.” A true and correct copy of the Pri-Med website is
14 attached as Exhibit D to this Second Amended Complaint.

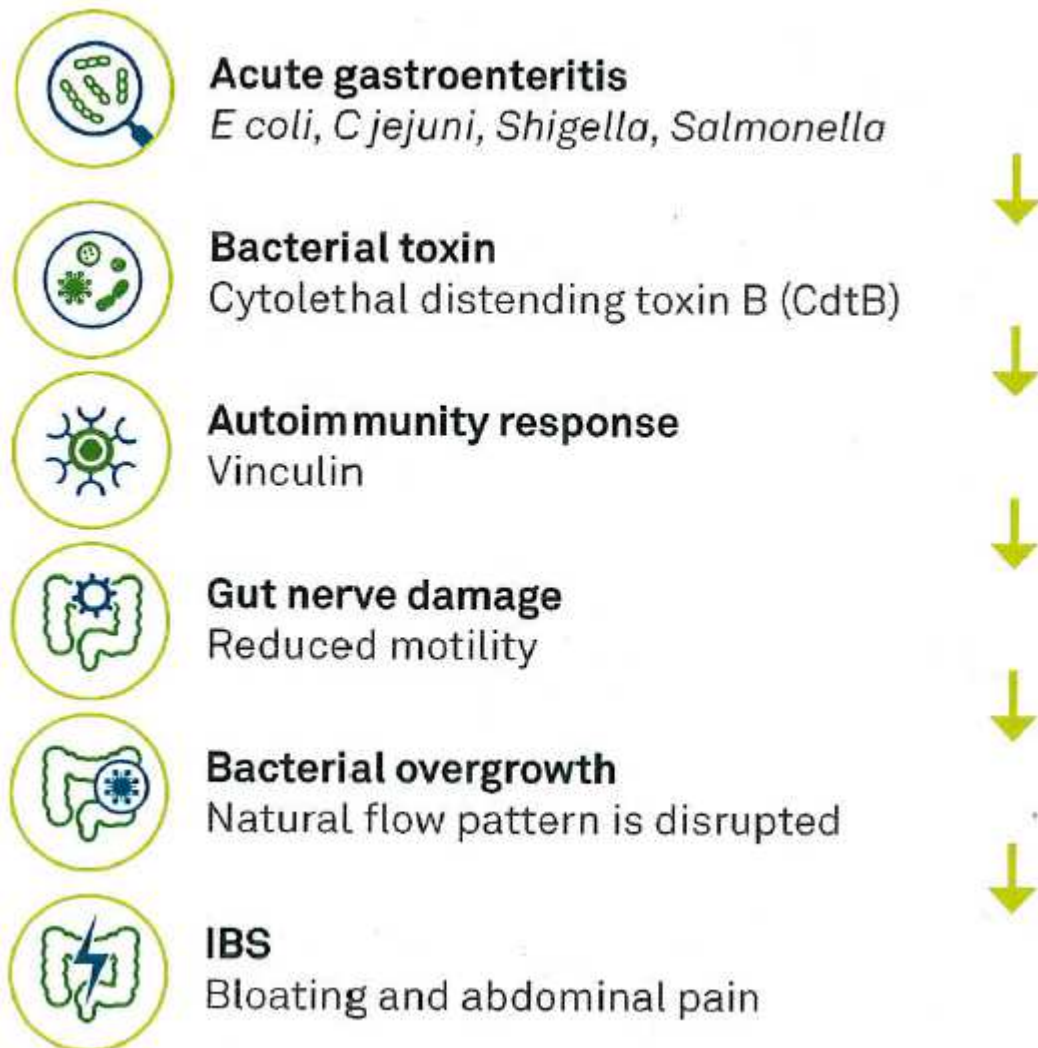
15 28. The Cedars-Sinai team further discovered that elevated anti-vinculin
16 antibodies are specific to IBS compared to inflammatory bowel disease (“IBD”) and
17 that an increase in anti-vinculin antibodies with respect to anti-CdtB antibodies
18 increases the specificity of this distinction.
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29. The pathophysiological sequence of IBS is illustrated in the following diagram created by Dr. Pimentel and shared with Quest subject to the Confidentiality Obligations:



30. Quest is improperly and without Cedars-Sinai's authorization using the foregoing in Quest's marketing and promotional materials for its IBSDETEX services, as reflected in the below graphic from a Quest brochure for IBSDETEX:

IBS-D/IBS-M pathophysiologic sequence



31. Prior to the Cedars-Sinai team's discovery, vinculin was not known or expected to be an antibody that is predictive of IBS over IBD and healthy controls. The Cedars-Sinai team discovered and demonstrated for the first time that after acute gastroenteritis, anti-CdtB antibodies through molecular mimicry produce an autoantibody to vinculin in IBS. Detection of anti-vinculin antibodies in the serum

1 of humans has important diagnostic value for IBS. At the time of the Cedars-Sinai
2 team's discovery, there was no existing diagnostic test for IBS using anti-vinculin
3 antibodies, or any other type of antibodies, on the market.

4 32. In addition, because vinculin is an intracellular protein, a diagnostic test
5 for IBS cannot utilize vinculin, as it occurs in the body, as the binding agent.
6 Rather, the vinculin must first be either purified or otherwise modified in order to
7 generate antigen substrate and anti-vinculin antibodies as the binding agent.

8 33. Beginning on February 11, 2009, Cedars-Sinai filed a series of
9 provisional patent applications for blood tests for IBS based on these discoveries
10 that ultimately matured into the '884 Patent, in addition to other patents in the
11 United States and in foreign jurisdictions.

12 **THE PARTIES' DISCUSSIONS**

13 34. In early November 2013, Cedars-Sinai and Quest began discussing a
14 potential license for Quest to commercialize Cedars-Sinai's IBS diagnostic
15 technology.

16 35. At least as early as or around November 24, 2013, Cedars-Sinai and
17 Quest mutually entered into the contractual Confidentiality Obligations to protect
18 the confidential and proprietary information exchanged in these discussions,
19 including all of the disclosures by Cedars-Sinai described in the following
20 paragraphs. The Confidentiality Obligations require the Parties, among other things,
21 to hold the disclosed proprietary information in the strictest confidence for five
22 years and not to use it for any purpose other than exploring the licensing
23 opportunity. At least the following Quest employees received Cedars-Sinai's
24 confidential and proprietary information through these discussions: Luke J.
25 Fleckenstein, a Director of Business Development at Quest; Dr. Stanley J. Naides,
26 then Medical Director and Interim Scientific Director of Immunology R&D at
27 Quest; and Cynthia D. Ray, a Director of Product Marketing at Quest.
28

1 36. On or about November 13, 2013, Cedars-Sinai sent Quest a copy of a
2 confidential presentation by Dr. Pimentel regarding Cedars-Sinai's research on
3 diagnosing IBS through detection of anti-CdtB and anti-vinculin antibodies.

4 37. On or about January 20, 2014, representatives of Cedars-Sinai and
5 Quest held a telephone call during which Dr. Pimentel disclosed to Quest
6 confidential details of Cedars-Sinai's IBS diagnostic technology. Following this
7 telephone call, Cedars-Sinai shared confidential copies of Cedars-Sinai's related
8 unpublished patent applications with Quest.

9 38. On or about March 7, 2014, representatives of Cedars-Sinai and Quest
10 held another telephone call during which Dr. Pimentel disclosed to Quest
11 confidential details of Cedars-Sinai's IBS diagnostic technology.

12 39. These discussions evidently persuaded Quest of the value of Cedars-
13 Sinai's IBS diagnostic technology, as on or about May 23, 2014, Quest sent Cedars-
14 Sinai a proposal for a license to Cedars-Sinai's IBS diagnostic technology.

15 40. On or about September 11, 2014, Cedars-Sinai sent Quest a copy of a
16 confidential manuscript of a paper submitted to the New England Journal of
17 Medicine by Cedars-Sinai regarding Cedars-Sinai's IBS diagnostic technology.

18 41. On or about September 29, 2014, representatives of Cedars-Sinai and
19 Quest held yet another telephone call during which Dr. Pimentel disclosed to Quest
20 confidential details of Cedars-Sinai's IBS diagnostic technology, including two
21 possible test methods that leverage inventions covered in Cedars-Sinai's then-
22 pending patent applications but are not themselves disclosed in the patent
23 applications, as well as how to validate tests based on the direct measurement of
24 anti-CdtB and anti-vinculin antibodies and how the same would serve unmet clinical
25 needs. These highly valuable, confidential insights were based on confidential
26 research and clinical validation data gathered over years in Dr. Pimentel's
27 laboratory.
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1 42. On or about October 4, 2014, Cedars-Sinai sent Quest a copy of a
2 confidential IBS diagnostic market research presentation detailing Cedars-Sinai's
3 assessment of the market opportunity for its IBS diagnostic technology and
4 strategies for increasing its acceptance and adoption by patients, physicians, and
5 payers. This included highly valuable and sensitive analysis of pricing and adoption
6 strategies for IBS diagnostics.

7 43. On or about October 28, 2014, Cedars-Sinai sent Quest copies of
8 another confidential, unpublished patent application relating to Cedars-Sinai's IBS
9 diagnostic technology. In this transmission, Cedars-Sinai additionally identified two
10 international patent applications relating to Cedars-Sinai's IBS diagnostic
11 technology: (1) International Patent Application No. PCT/US2010/023911, filed
12 February 11, 2010, titled "Antibody to Cytolethal Distending Toxin of
13 *Campylobacter Jejuni*" ("the '911 PCT Application"), and (2) International Patent
14 Application No. PCT/US2013/055626, filed August 19, 2013, titled "Diagnosis and
15 Treatment of Motility Disorders of the Gut and Bladder, and of Fibromyalgia" ("the
16 '626 PCT Application"). Both international patent applications designated the
17 United States. The United States National Phase of the '626 PCT Application
18 ultimately issued as the '884 Patent.

19 **QUEST'S UNLAWFUL CONDUCT**

20 44. On or about December 23, 2014, after Quest obtained all of the above-
21 discussed confidential and proprietary information from Cedars-Sinai, Quest
22 informed Cedars-Sinai that Quest was not interested in taking a license.

23 45. Consequently, on or about February 3, 2015, Cedars-Sinai entered into
24 a license with a different diagnostic service provider, Commonwealth Laboratories,
25 for Cedars-Sinai's IBS diagnostic technology. In view of the license Cedars-Sinai
26 granted to Commonwealth Laboratories and the lack of a license between Cedars-
27 Sinai and Quest, Quest did not have the right to practice Cedars-Sinai's technology
28 in the provision of IBS diagnostic services.

1 46. In recognition of the value of Cedars-Sinai's technology and the
2 underlying license, Quest had Commonwealth Laboratories perform licensed
3 diagnostic services on samples collected through Quest's patient service centers.

4 47. Cedars-Sinai since learned that on or about July 9, 2015, Quest filed an
5 application to register the trademark IBSDTEX in the United States Patent and
6 Trademark Office, Application Serial No. 86688260, based on an intent to use the
7 mark in commerce for "medical diagnostic testing services; medical information
8 services" in International Class 044. A true and correct copy of U.S. Trademark
9 Application Serial No. 86688260 is attached as Exhibit E to this Second Amended
10 Complaint. On information and belief, therefore, as of and before July 9, 2015,
11 Quest was creating, designing, developing, and/or using an IBS assay and/or doing
12 IBS testing and/or making preparations for delivery of IBS services and the use of
13 an IBS assay or diagnostic.

14 48. And in or about April 2017, Cedars-Sinai discovered that Quest is itself
15 performing, under the IBSDTEX mark it applied to register nearly two years
16 before, IBS diagnostic testing services. Upon information and belief, the Nichols
17 Institute, a wholly-owned subsidiary of Quest, performs IBS diagnostic services on
18 samples collected through Quest's patient service centers.

19 49. Upon information and belief, Quest's diagnostic IBS testing services
20 and IBS testing are based on unauthorized and unlawful use of Cedars-Sinai's
21 patented inventions, trade secrets, and other confidential information subject to the
22 Confidentiality Obligations, without any authorization by or compensation to
23 Cedars-Sinai.

24 50. Upon information and belief, Quest had been planning and preparing to
25 provide these lucrative services in blatant violation of Cedars-Sinai's rights for a
26 significant period of time before launching the diagnostic IBS testing services and
27 IBS testing, publicly.
28

FIRST CLAIM FOR RELIEF

(Trade Secret Misappropriation, 18 U.S.C. § 1836 *et seq.*)

51. Cedars-Sinai repeats and realleges the allegations of the foregoing Paragraphs 1 through 50 as if fully set forth herein.

52. Cedars-Sinai is the owner of financial, business, scientific, technical, economic, and/or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, tangible and/or intangible, related to IBS diagnostic techniques and validation of the same, as well as how to serve unmet clinical needs associated with IBS (“Trade Secrets”).

53. Cedars-Sinai has taken reasonable measures to keep the Trade Secrets secret. Such measures include controlling access to the Trade Secrets by practical means as well as legal means, such as the Confidentiality Obligations under which Trade Secrets were disclosed to Quest.

54. Cedars-Sinai’s Trade Secrets derive independent economic value, actual and/or potential, from not being generally known to, and not being readily ascertainable through proper means by, other persons who can obtain economic value from the disclosure or use of the information.

55. At all relevant times, Quest knew or had reason to know that its knowledge of Cedars-Sinai’s Trade Secrets was acquired under circumstances giving rise to a duty to maintain the secrecy of the Trade Secrets or limit the use of the Trade Secrets.

56. Upon information and belief, Quest misappropriated Cedars-Sinai’s Trade Secrets by disclosing and/or using the Trade Secrets without express or implied consent of Cedars-Sinai in connection with Quest’s development, commercialization, and performance of Quest’s IBSDTEX diagnostic services.

57. Cedars-Sinai has suffered, and continues to suffer, damages, including without limitation damages for actual loss caused by the misappropriation of the

1 Trade Secrets, damages for unjust enrichment of Quest caused by the
 2 misappropriation of the Trade Secrets, damages caused by the misappropriation
 3 measured by imposition of liability for a reasonable royalty for Quest's
 4 misappropriation, and/or disgorgement of profits. The harm to Cedars-Sinai is
 5 further irreparable and continuing.

6 58. Upon information and belief, Quest willfully and maliciously
 7 misappropriated the Trade Secrets, entitling Cedars-Sinai to exemplary damages in
 8 an amount of 2 times the amount of the compensatory damages plus Cedars-Sinai's
 9 reasonable attorney's fees incurred to vindicate its rights in this action.

10 **SECOND CLAIM FOR RELIEF**

11 **(Trade Secret Misappropriation, Cal. Civ. Code § 3426 *et seq.*)**

12 59. Cedars-Sinai repeats and realleges the allegations of the foregoing
 13 Paragraphs 1 through 58 as if fully set forth herein.

14 60. Cedars-Sinai is the owner of the Trade Secrets.

15 61. Cedars-Sinai's Trade Secrets derive independent economic value,
 16 actual and/or potential, from not being generally known to the public or to other
 17 persons who can obtain economic value from their disclosure or use.

18 62. Cedars-Sinai's Trade Secrets were at all relevant times the subject of
 19 efforts that are reasonable under the circumstances to maintain their secrecy. Such
 20 efforts include controlling access to the Trade Secrets by practical means as well as
 21 legal means, such as the Confidentiality Obligations under which Trade Secrets
 22 were disclosed to Quest.

23 63. At all relevant times, Quest knew or had reason to know that its
 24 knowledge of the Trade Secrets was acquired under circumstances giving rise to a
 25 duty to maintain their secrecy or limit their use.

26 64. Upon information and belief, Quest and the Nichols Institute
 27 misappropriated Cedars-Sinai's Trade Secrets by disclosing and/or using the Trade
 28 Secrets without express or implied consent of Cedars-Sinai in connection with

1 Quest's and the Nichols Institute's development and commercialization of Quest's
2 and the Nichols Institute's IBSDETEX diagnostic services.

3 65. Cedars-Sinai has suffered, and continues to suffer, damages, including
4 without limitation damages for actual loss caused by the misappropriation of the
5 Trade Secrets, damages for unjust enrichment of Quest and the Nichols Institute
6 caused by the misappropriation of the Trade Secrets, damages caused by the
7 misappropriation measured by imposition of liability for a reasonable royalty for
8 Quest's and the Nichols Institute's misappropriation, and/or disgorgement of profits.
9 The harm to Cedars-Sinai is further irreparable and continuing.

10 66. Upon information and belief, Quest and the Nichols Institute willfully
11 and maliciously misappropriated the Trade Secrets, entitling Cedars-Sinai to
12 exemplary damages in an amount of twice the amount of the compensatory damages
13 plus Cedars-Sinai's reasonable attorney's fees incurred to vindicate its rights in this
14 action.

15 **THIRD CLAIM FOR RELIEF**

16 **(Breach of Contract)**

17 67. Cedars-Sinai repeats and realleges the allegations of the foregoing
18 Paragraphs 1 through 66 as if fully set forth herein.

19 68. Cedars-Sinai and Quest entered into a valid and binding contract giving
20 rise to the Confidentiality Obligations.

21 69. Cedars-Sinai performed all, or substantially all, of its material
22 obligations under the contract.

23 70. Quest and the Nichols Institute disclosed and/or used Cedars-Sinai's
24 proprietary, confidential information that was disclosed to Quest under the contract
25 in violation of the terms of the contract.

26 71. Cedars-Sinai has suffered, and continues to suffer, damages for actual
27 loss caused by Quest's breach of the contract, including lost profits, and/or damages
28 for unjust enrichment of Quest and the Nichols Institute caused by the breach of the

1 contract.

2 **FOURTH CLAIM FOR RELIEF**

3 **(Infringement of U.S. Patent No. 9,702,884)**

4 72. Cedars-Sinai repeats and realleges the allegations of the foregoing
5 Paragraphs 1 through 71 as if fully set forth herein.

6 73. Quest and the Nichols Institute have infringed claims 3, 4, 9, and 10 of
7 the '884 Patent under the Patent Laws of the United States, 35 U.S.C. § 271 *et seq.*
8 Quest and the Nichols Institute have directly infringed claims 3, 4, 9, and 10 of the
9 '884 Patent under 35 U.S.C. § 271(a), literally and/or under the doctrine of
10 equivalents, in connection with Quest's IBSDETEX services. As required in claim
11 3, Quest and the Nichols Institute provide a system for diagnosing irritable bowel
12 syndrome comprising an isolated biological sample from a subject desiring
13 diagnosis regarding irritable bowel syndrome (IBS). And as required in claim 3,
14 Quest's and the Nichols Institute's system comprises an assay for detecting in the
15 biological sample, a level of an anti-vinculin antibody. As required in claim 4,
16 Quest and the Nichols Institute provide a system for diagnosing irritable bowel
17 syndrome wherein the assay is an enzyme-linked immunosorbent assay (ELISA),
18 wherein the ELISA comprises using vinculin, SEQ ID NO:1 or a fragment thereof
19 as a substrate or reagent to bind the anti-vinculin antibody. As required in claim 9,
20 Quest and the Nichols Institute provide a system, comprising an isolated biological
21 sample from a subject desiring a diagnosis to distinguish between irritable bowel
22 syndrome (IBS) and inflammatory bowel disease (IBD). And as required in claim 9,
23 Quest's and the Nichols Institute's system comprises an assay for detecting in the
24 biological sample, a level of an anti-vinculin antibody. As required in claim 10,
25 Quest and the Nichols Institute provide a system wherein the assay is an enzyme-
26 linked immunosorbent assay (ELISA), wherein the ELISA comprises using
27 vinculin, SEQ ID NO:1 or a fragment thereof as a substrate or reagent to bind the
28 anti-vinculin antibody.

74. Quest has induced infringement of claims 3, 4, 9, and 10 of the '884 Patent under 35 U.S.C. § 271(b) in connection with Quest's IBSDETEX services. Quest had knowledge of the patented inventions of the '884 Patent as of at least October 28, 2014. On information and belief, Quest also had knowledge of the patent application(s) corresponding to the '884 Patent and had knowledge that its IBSDETEX services infringe, literally and/or under the doctrine of equivalents, claims 3, 4, 9, and 10 of the '844 Patent as of at least the date of issuance of the '884 Patent on July 11, 2017. Quest has induced and encouraged the direct infringement of the '884 Patent by the Nichols Institute by intentionally directing the Nichols Institute and encouraging the Nichols Institute to make and/or use within the United States and/or to import into the United States testing kits for the IBSDETEX services, which embody the patented inventions of the '884 Patent. Quest is therefore liable for indirect infringement of the '884 Patent pursuant to 35 U.S.C. § 271(b).

75. Quest's and the Nichols Institute's infringement is and has been willful. Quest and the Nichols Institute had knowledge of the patented inventions of the '884 Patent as of at least October 28, 2014. On information and belief, Quest and the Nichols Institute had knowledge of the patent application(s) corresponding to the '884 Patent and had knowledge that their IBSDETEX services infringe claims 3, 4, 9, and 10 of the '844 Patent as of at least the date of issuance of the '884 Patent on July 11, 2017.

76. Cedars-Sinai has been damaged and continues to be damaged, in an amount to be determined, as a direct and proximate result of Quest's and the Nichols Institute's infringement of the '884 Patent. The harm to Cedars-Sinai is further irreparable and continuing.

PRAAYER FOR RELIEF

WHEREFORE, Cedars-Sinai respectfully requests the Court to enter judgment in favor of Cedars-Sinai and against Quest and the Nichols Institute as to

all claims asserted herein as follows:

First Claim for Relief:

- A. Granting a judgment that Quest and the Nichols Institute misappropriated Cedars-Sinai's Trade Secrets under 18 U.S.C. § 1836 *et seq.*;
- B. Granting injunctive relief, including a permanent injunction to prevent all future actual and threatened misappropriation of Cedars-Sinai's Trade Secrets; and
- C. Ordering Quest and the Nichols Institute to pay damages to Cedars-Sinai for all losses and injuries, including:
 - i. Damages for Cedars-Sinai's lost revenues caused by Quest's and the Nichols Institute's misappropriation of the Trade Secrets;
 - ii. Disgorgement of Quest's and the Nichols Institute's profits and/or other unjust enrichment caused by Quest's and the Nichols Institute's misappropriation of the Trade Secrets; and/or
 - iii. A reasonable royalty for Quest's and the Nichols Institute's unauthorized disclosure and/or use of Cedars-Sinai's Trade Secrets;
- D. Awarding exemplary damages in an amount 2 times the amount of damages awarded under paragraph (C) above;
- E. Awarding to Cedars-Sinai its reasonable attorney's fees and costs incurred in this matter, together with pre-judgment and post-judgment interest and costs as fixed by the Court; and
- F. For any and all other relief in accordance with proof or which is equitable and proper.

Second Claim for Relief:

- A. Granting a judgment that Quest and the Nichols Institute misappropriated Cedars-Sinai's Trade Secrets under Cal. Civ. Code § 3426 *et seq.*;

- 1 B. Granting injunctive relief, including a permanent injunction to prevent
 2 all future actual and threatened misappropriation of Cedars-Sinai's
 3 Trade Secrets;
- 4 C. Ordering Quest and the Nichols Institute to pay damages to Cedars-
 5 Sinai for all losses and injuries, including:
- 6 i. Damages for Cedars-Sinai's lost revenues caused by Quest's and the
 7 Nichols Institute's misappropriation of the Trade Secrets;
- 8 ii. Disgorgement of Quest's and the Nichols Institute's profits and/or
 9 other unjust enrichment caused by Quest's and the Nichols
 10 Institute's misappropriation of the Trade Secrets; and/or
- 11 iii. A reasonable royalty for Quest's and the Nichols Institute's
 12 unauthorized disclosure and/or use of Cedars-Sinai's Trade Secrets;
- 13 D. Awarding exemplary damages in an amount 2 times the amount of
 14 damages awarded under paragraph (C) above;
- 15 E. Awarding to Cedars-Sinai its reasonable attorney's fees and costs
 16 incurred in this matter, together with pre-judgment and post-judgment
 17 interest and costs as fixed by the Court; and
- 18 F. For any and all other relief in accordance with proof or which is
 19 equitable and proper.

20 **Third Claim for Relief:**

- 21 A. Granting a judgment that Quest breached the contract giving rise to the
 22 Confidentiality Obligations;
- 23 B. Ordering Quest to pay damages to Cedars-Sinai for all losses and
 24 injuries, including compensatory damages for Cedars-Sinai's lost
 25 revenues caused by Quest's breach of the Confidentiality Obligations
 26 sufficient to put Cedars-Sinai in as good a position as it would have
 27 been had performance been rendered by Quest as promised;
- 28 C. Ordering Quest to pay Cedars-Sinai's attorney fees, incurred here,

pursuant to California Code of Civil Procedure § 1021.5;

D. Awarding to Cedars-Sinai pre-judgment and post-judgment interest and costs as fixed by the Court; and

E. For any and all other relief in accordance with proof or which is equitable and proper.

Fourth Claim for Relief

A. Granting a judgment that Quest and the Nichols Institute have directly infringed the '884 Patent in violation of 35 U.S.C. § 271(a);

B. Granting a judgment that Quest has indirectly infringed the '884 Patent in violation of 35 U.S.C. § 271(b);

C. Ordering Quest and the Nichols Institute to pay damages to Cedars-Sinai for all losses and injuries, including damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the patented inventions by Quest and the Nichols Institute, together with pre-judgment and post-judgment interest and costs as fixed by the Court, in accordance with 35 U.S.C. § 284 and 35 U.S.C. § 154(d);

D. Granting a judgment that Quest's and the Nichols Institute's infringement was willful and ordering Quest and the Nichols Institute to pay to Cedars-Sinai increased damages of three times the compensatory damages, in accordance with 35 U.S.C. § 284;

E. For injunctive relief, including a permanent injunction;

F. Granting a judgment that this case is exceptional under 35 U.S.C. § 285 and ordering Quest and the Nichols Institute to pay to Cedars-Sinai its reasonable attorney's fees incurred in this action; and

G. Granting Cedars-Sinai such other and further relief in accordance with proof or which this Court may deem equitable and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38 and Central District of California L.R. 38-1, Cedars-Sinai demands a trial by jury on all issues so triable.

Dated: November 16, 2017

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